中華民國專利公報 [19] [12]

[11]公告編號：400227
[44]中華民國　89 年 (2000)　08 月 01 日
發明　　　　全 2 頁

[51] Int.Cl 06: A61F13/02

91110802

[54]名　稱：消毒設備及其使用方法
[21]申請案號：087118655　[22]申請日期：中華民國　87年 (1998)　11 月 10 日
[30]優 先 權：[31]08/969.590　[32]1997/11/13　[33]美國

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[57]申請專利範圍：

1.一種消毒設備，包含：
一內側消毒包紮物：以及
一在使用外側消毒袋，其包含一外部表面以及一內部表面，其界定為具有接收內側消毒包紮物及消毒物之開口的袋子，其中此袋子由可吸入及非織造材料所製造。

2.如申請專利範圍第 1 項的設備，更進一步包含大體上藉內側包紮物包圍的消毒盤。

3.如申請專利範圍第 1 項的設備，更進一步包含在內側消毒包紮物或外側消毒袋的抗靜電處理。

4.如申請專利範圍第 1 項的設備，其中此外側袋為駐極體。

5.如申請專利範圍第 1 項的設備，其中此內側包紮物為駐極體。

6.如申請專利範圍第 1 項的設備，其中此內側包紮物與外側袋為駐極體。

7.如申請專利範圍第 1 項的設備，有至少提供 85%細菌過濾效率至消毒物的可能。

8.如申請專利範圍第 1 項的設備，也至少提供 90%細菌過濾效率至消毒物的可能。

9.如申請專利範圍第 1 項的設備，有至少提供 95%細菌過濾效率至消毒物的可能。

10.如申請專利範圍第 1 項的設備，其中此材料為聚烴。

11.如申請專利範圍第 10 項的設備，其中此材料包含介於第一及第二紡黏層之間的熔噴法非織造層：

12.如申請專利範圍第 11 項的設備，其中此材料為介於 0.6～ 6 盎司／平方碼之間。

13.如申請專利範圍第12項的設備，其中紡黏層為介於0.25～2.0 盎司／平方碼之間，另外熔噴法非織造層為介於0.1‘2.0盎司／平方碼之間。

14.如申請專利範圍第11項的設備，其中此材料為2.2盎司／平方碼。

15.如申請專利範圍第14項的設備，其中紡黏層為0.85盎司／平方碼，另外熔噴法非織造層為0.5盎司／平方碼。

16.如申請專利範圍第1項的設備，其中此袋是由材料折疊及超音波側密閉的薄片。

17.一種使用消毒設備的方法，其包含：

(a)置放物體於內部消毒包紮物的內側：

(b)在消毒包紮物範圍內將物體插入可再使用的外側消毒袋，前述的袋子包含一外部表面及一內部表面，其界定為

具有接收內側消毒包紮物及消毒物的口袋。其中此袋乃由可吸入及非織造材料所製造：以及

(c)消毒此物體。

18.如申請專利範圍第17項的方法，其中此內側消毒包紮物與／或者外側消毒袋為駐極體，且更進一步包含在內側消毒包紮物與／或者外側消毒袋的抗靜電處理。

19.如申請專利範圍第17項的方法，其中此外側消毒袋至少提供85%細菌過濾效率至消毒物的可能。

20.如申請專利範圍第17項的方法，其中此材料包含介於第一和第二聚烴紡黏層之間的聚烴熔噴法非織造層，其中紡黏層為介於0.25～2.0盎司／平方碼之間，另外熔噴法非織造層為介於0.1～2.0盎司／平方碼之間。

YCF-023TW

87118655

PK-0964598
K-C Case 12588

STERILIZATION WRAP AND PROCEDURES

Field of the Invention

This invention relates in general to the field of materials suitable for sterilizing and containing objects, typically for use in the medical industry.

Background of the Invention

The sterilization of medical equipment and supplies is vital to minimizing the spread of harmful or infectious agents to patients. The medical equipment or supplies in need of sterilization include, for example, clamps, scalpel blade handles, retractors, forceps, scissors, basins or towels. Typically, the object desired to be sterilized is placed on an instrument tray and packaged within at least one layer of a sterilization wrap. The wrapped object is then sterilized within the sterilization wrap by a variety of methods, e.g. steam autoclaving, plasma sterilization, microwave irradiation, etc. Sterility of the object is typically maintained by keeping the sterilization wrap package sealed until immediately prior to use.

In the field of sterilization wraps, many designs have been provided which attempt to permit the penetration of a sterilant therethrough, while minimizing the subsequent entry of any contaminates. The type of sterilization technique employed may dictate the materials used. For, example, where gamma or other radiation is used to sterilize the contents, the sterilization wrap may be sealed and made impermeable to even gases. However, when plasma sterilization, steam, ethylene oxide or other attenuating gases, are used to sterilize an item, the sterilization wrap must be gas permeable or breathable. This presents a challenge to construct a breathable sterilization wrap that minimizes the entry of any contaminates, e.g. bacteria, following the sterilization procedure.

Many prior art sterilization wraps require permanent sealing of the sterilization wrap around the object to be sterilized. Therefore, in order to access and use the sterilized object, these prior art sterilization wraps must be torn open. Moreover, prior art sterilization wraps are typically sheets which are wrapped into position and secured by tape or other adhesive fastening means. An alternative approach would be to provide an outer sterilization wrap that maintains the wrapped conformation of the inner wrap. These and other objects of the invention will be apparent to those skilled in the art.

Summary of the Invention

The present invention provides a sterilization device comprising an inner sterilization wrap and a re-usable outer sterilization bag. The re-usable outer sterilization bag has an outside surface and an inside surface defining a pouch with an opening for receiving the inner sterilization wrap and a sterilizable object. The material is preferably a spunbonded or meltblown polyolefin fiber non-woven, breathable web. The present invention also provides methods of sterilizing an object, and methods of using a sterilizable bag.

Detailed Description of the Invention

As used herein the term "sterilization" refers to a wide variety of techniques employed to attenuate, kill or eliminate infectious agents. For example, sterilization contemplates gas plasma sterilization, such as described in U.S. Patent No. 4,801,427, in addition to steam sterilization, ethylene oxide sterilization, and irradiation.

As used herein the term "polymer" generally includes but is not limited to, homopolymers, copolymers (such as for example, block, graft random and alternating copolymers), terpolymers, etc. and blends and modifications thereof. Furthermore, unless otherwise specifically limited, the term "polymer" shall include all possible geometrical configurations of the material. These configurations include, but are not limited to isotactic, syndiotactic and random symmetries.

As used herein the term "microfibers" means small diameter fibers having an average diameter not greater than about 75 microns, for example, having an average diameter of from about 0.5 microns to about 50 microns, or more particularly, microfibers may have an average diameter of from about 2 microns to about 40 microns.

As used herein the term "nonwoven fabric or web" means a web having a structure of individual fibers or threads which are interlaid, but not in an identifiable manner as in a knitted fabric. Nonwoven fabrics or webs have been formed from many processes such as for example, meltblowing processes, spunbonding processes, and bonded carded web processes.

As used herein the term "spunbonded fibers" refers to small diameter fibers which are formed by extruding molten thermoplastic polymer material as filaments from a plurality of fine, usually circular capillaries of a spinnerette with the diameter of the extruded filaments then being rapidly reduced as by, for example, in U.S. Patent No. 4,340,563 to *Appel et al.*, and U.S. Patent No. 3,692,618 to *Dorschner et al.*, U.S. Patent

No. 3,802,817 to *Matsuki et al.*, U.S. Patent Nos. 3,338,992 and 3,341,394 to *Kinney*, U.S. Patent Nos. 3,502, 763 and 3,909,009 to *Levy*, and U.S. Patent No. 3,542,615 to *Dobo et al.* Spunbonded fibers are generally continuous and larger than 7 microns, more particularly, having an average diameter of greater than 10 microns.

As used herein the term "meltblown fibers" means fibers formed by extruding a molten thermoplastic polymer through a plurality of fine, usually circular, die capillaries as molten threads or filaments into a high velocity gas (e.g. air) stream which attenuates the filaments of molten thermoplastic polymer material to reduce their diameter, which may be to microfiber diameter. Thereafter, the meltblown fibers are carried by the high velocity gas stream and are deposited on a collecting surface to form a web of randomly disbursed meltblown fibers. Such a process is disclosed, for example, in U.S. Patent No. 3,849,241 and U.S. Patent No. 3,978,185.

The meltblowing process generally uses an extruder to supply melted polymer to a die tip where the polymer is fiberized as it passes through fine openings, forming a curtain of filaments. The filaments are drawn pneumatically and deposited on a moving foraminous mat, belt or "forming wire" to form the nonwoven fabric. Nonwoven fabrics may be measured in ounces per square yard (osy) or grams per square meter (gsm). (Multiplying osy by 33.91 yields gsm.)

The fibers produced in the meltblowing process are generally in the range of from about 0.5 to about 10 microns in diameter, depending on process conditions and the desired end use for the fabrics to be produced from such fibers. For example, increasing the polymer molecular weight or decreasing the processing temperature results in larger diameter fibers. Changes in the quench fluid temperature and pneumatic draw pressure can also affect fiber diameter. Finer fibers are generally more desirable as they usually produce greater barrier properties in the fabric into which they are made.

The fabric of this invention may be used in a single layer embodiment or as a multilayer laminate incorporating the fabric of this invention. Such a laminate may be formed by a number of different techniques including but not limited to using adhesive, needle punching, ultrasonic bonding, print bonding, thermal calendering and any other method known in the art. Such a multilayer laminate may be an embodiment wherein some of the layers are spunbonded and some meltblown such as a spunbonded/meltblown (SM) laminate or a spunbonded/meltblown/spunbonded (SMS) laminate, as disclosed in U.S. Pat. No. 4,041,203 to *Brock et al.* and U.S. Pat. No. 5,169,706 to *Collier, et al.* or wherein some of the layers are made from staple fibers.

The fibers used in the other layers may be polyethylene, polypropylene or bicomponent fibers. One useful source of such a SMS laminate is commercially available from the Kimberly-Clark Corporation as KIMGUARD® sterile wrap.

An SMS laminate, for example, may be made by sequentially depositing onto a moving conveyor belt or forming wire first a spunbonded fabric layer, then a meltblown fabric layer and last another spunbonded layer and then bonding the laminate in a manner described above. Alternatively, the three fabric layers may be made individually, collected in rolls, and combined in a separate bonding step.

In re-usable applications, when the fabric of this invention is an SMS laminate, it has been found to be advantageous to "prebond" one of the spunbonded layers. Pre-bonding is a step of (thermally) bonding a layer by itself using a pattern of 8 to 50% bond area or more particularly a pattern of about 25% bond area with many small pins. In these situations, pre-bonding is advantageous with polyolefin webs because of the relatively high heat of fusion and low melting point of polyolefin. It is believed that in order to supply enough heat to a polyolefin web to bond it, the heat addition must be done sufficiently slowly to avoid excessively melting the web and causing it to stick to the calendar rolls. Pre-bonding one of the spunbonded layers helps to reduce the intensity of temperature the laminate must be subjected to in the bonding step.

Pre-bonding also provides the material with greater abrasion resistance though it can reduce the drapeability somewhat. Since it is an objective of this invention that the material provide good barrier properties yet be soft and drapeable, pre-bonding should be kept to a minimum. Pre-bonding is optional, and if desired should be restricted to only one layer for this reason.

After pre-bonding, the spunbonded layer may then be combined with unbonded meltblown and spunbonded layers and bonded with a more open bond pattern like the one mentioned above, preferably with a pattern having relatively larger pins. The temperature of bonding will vary depending on the exact polymers involved, the degree and strength of bonding desired, and the final use of the fabric.

The layers of the fabric of this invention may also contain fire retardants for fire safety, or pigments to give each layer the same or distinct colors. Fire retardants and pigments for spunbonded and meltblown thermoplastic polymers are known in the art and are usually internal additives. A pigment, if used, is generally present in an amount less than 5 weight percent of the SMS composite.

The material of this invention may also have topical treatments applied to it for more specialized functions. Such topical treatments and their methods of application are known in the art and include, for example, alcohol repellency treatments, anti-static treatments and the like, applied by spraying, dipping, etc. An example of such a topical treatment is the application of ZELEC® antistatic neutralized mixed alkyl phosphates (available from E.I. DuPont, Wilmington, Del.).

The present invention provides a sterilization device comprising an inner sterilization wrap and a re-usable outer sterilization bag. The re-usable outer sterilization bag has an outside surface and an inside surface defining a pouch with an opening for receiving the inner sterilization wrap and a sterilizable object. In one embodiment, the bag may be formed from a single sheet of gas-permeable, or breathable, non-woven material.

As used herein, the term "breathable" refers to material which is permeable to water vapor having a minimum water vapor transmission rate (WVTR) of about 300 $g/m^2/24$ hours, calculated in accordance with ASTM Standard E96-80.

In preferred embodiments, a commonly available sterilization indicator can be placed within the sterilization bag for easy determination of the sterilization status of the contents therein.

The present invention provides at least about an 85% bacterial filtration efficiency to the sterilizable object. More preferably, the present invention provides at least about an 90% bacterial filtration efficiency to the sterilizable object, and most preferably at least about an 95% bacterial filtration efficiency to the sterilizable object.

The invention provides that the material of the sterilization bag can be constructed of polyolefin. In preferred embodiments, the material of the outer bag and/or the inner sterilization wrap can be preferably a SMS laminate, that can be electreted as described for example in U.S. Patent No. 5,401,446. Electreting involves subjecting the material to a pair of electrical fields having opposite polarities. Each electrical field forms a corona discharge which is imparted to the material. Other means of electreting the material are well-known, such as thermal, liquid contact and electron beam methods.

In preferred embodiments, the material of the sterilization bag comprises a meltblown layer between first and second spunbonded layers. Preferably, the material is